Case Note

Environmental Law Review

Renewal of an active substance found in an insecticide: How to articulate risk assessment and risk management?

Environmental Law Review
1–8

DOI: 10.1177/14614529241292129
journals.sagepub.com/home/elj
Sage

Nicolas de Sadeleer
Professor of EU Law and Jean Monnet Chair, UCLouvain, St Louis, Belgium

Abstract
In *Pesticide Action Network Europe* v *Commission* (Case T-536/22), Pesticide Action Network Europe (PAN Europe) contested the renewal by the European Commission of the active substance cypermethrin. This substance is used or is marketed as an insecticide in large-scale commercial agricultural applications as well as in consumer products for domestic purposes (ant and cockroach killer). PAN Europe sought the annulment of the European Commission's decision of 23 June 2022 by which the latter rejected the request for internal review made by PAN Europe in accordance with Regulation (EC) No. 1367/2006 on the application of the provisions of the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters. The applicant argued, in essence, that where a risk is established with sufficient certainty by the European Food Safety Authority (EFSA), the Commission could not disregard the conclusions of the scientific assessment by relying on its powers as risk manager. In stressing the discretion enjoyed by the Commission, the General Court dismissed the action of PAN Europe. This casenote suggests that the General Court applied the precautionary principle too formally.

Keywords
Plant-protection products, renewal of the active substance cypermethrin, risk assessment and risk management, identification of critical areas of concern by EFSA, missing information, precautionary principle, ex post Member States risk mitigation measures, discretion enjoyed by the commission, judicial restraint in reviewing the exercise of the commission's discretionay power

Introduction

The European Union (EU) chemicals policy has historically been related to a general preference for a certainty-seeking regulatory style in which a formal, science-based, and standardised risk assessment (RA) has been singled out as the predominant tool for decision-making. However, while RAs draw

Corresponding author:
Nicolas de Sadeleer, Professor of EU Law and Jean Monnet Chair, UCLouvain, St Louis, Belgium.
Email: nicolas.desadeleer@uclouvain.be

extensively on science, data are often incomplete and results may be unclear or contradictory. Indeed, as it is difficult to establish causal links between exposure to chemicals and health or environmental effects, there is generally a significant degree of uncertainty in estimates of the probability and magnitude of adverse effects associated with a chemical agent. The variety and complexity pathways of dispersion in the environment, and the bio-accumulation in the food chain are likely to compound these uncertainties. In addition, chemical substances have different properties which may give rise to risks of a different nature.[1]

As the result of limited knowledge, it is difficult to provide conclusive evidence of a threat to human health or to the environment. In particular, endocrine disrupting substances (EDS) mimicking hormones have challenged the scientific belief that high doses produce more serious effects than low ones.[2] In this regard, the implementation of Regulation 1107/2009 concerning the placing of plant protection products on the market (hereafter 'PPPR') has given rise to a considerable body of litigation on the placing on the market of both active substances and pesticides. The PPPR pursues a twofold approach.

On the one hand, it vests the EU authorities with exclusive competence over the assessment of the active substances found in these products,[3] as well as the inclusion of these substances in an EU list adopted in accordance with the comitology procedure.[4] On the other hand, national authorities are called on to grant marketing authorisations for the products concerned in accordance with the PPPR.[5] As part of this process, they must carry out independent, objective and transparent assessments of the application of these products in the light of current scientific and technical knowledge.[6] It will come as no surprise that the procedures applicable to the assessment of active substances and the authorisation of plant protection products are closely linked in that, in particular, the authorisation of a plant protection product presupposes, pursuant to article 29(1)(a) of the PPPR, that its active substances have previously been approved by the European Commission.[7] It is important to note that scientific expertise underpins the overall decision-making process.[8]

In accordance with the principle of mutual recognition, authorisations granted by one Member State must be accepted by the other Member States where agricultural, plant health and environmental (including climatic) conditions are comparable. In order to facilitate such mutual recognition, Commission Implementing Regulation (EU) No 844/2012 divides up the Union into three zones (north, centre and south) with comparable environmental and climatic characteristics.[9] Mutual recognition is the basic rule in each of these zones, within which plant protection products authorised by any Member State will automatically be declared eligible for use in the other Member States of the respective zone.

Articulating scientific expertise and the regulatory outcome

The annotated judgment, *PAN Europe* v *Commission*, which was issued by the General Court on 21 February 2024 (Case T-536/22), concerned the renewal of the approval of an active substance, cypermethrin, for which

1. Case C-419/17P *Deza a.s. v European Chemicals Agency* [2019] C:2019:52, at [37].
2. See e.g., Case T 31/07 *Du Pont de Nemours (France) and Others v Commission* [2013] T:2013:167.
3. Ibid. at [203]
4. See PPPR, Chapter II.
5. PPPR, art 3(1).
6. Ibid. arts 11(2) and 36(1).
7. Case C-616/17 *Blaise and Others* [2019] EU:C:2019:800, at [66].
8. See Case T–536/22 *Pesticide Action Network Europe (PAN Europe) v Commission* [2024] T:2024:98, at [50], [65], [78], [79] and [81].
9. See PPPR, recital 23, art 40 and Annex IV.

substitution is envisaged in accordance with the PPPR.[10] Cypermethrin is a broad-spectrum insecticide used in large-scale commercial agricultural applications. In November 2021, following years of discussions among the European Commission, the Member States and the European Food Safety Authority (EFSA),[11] cypermethrin was re-approved by the Commission for seven years. The Pesticide Action Network Europe (PAN Europe) brought an action before the General Court of the EU seeking the annulment of the European Commission's decision to reject its request for an internal review, which it had submitted in accordance with article 10 of Aarhus Regulation 1367/2006, of Implementing Regulation 2021/2049 renewing the approval of cypermethrin.[12]

This case is testament to the difficulties that arise in articulating scientific expertise (risk assessment) and the regulatory outcome (risk management), both of which are underpinned by the precautionary principle (PP) proclaimed in article 191(2) of the Treaty on the Functioning of the European Union (TFEU).[13] The PP is a general principle of EU law requiring the authorities in question, in the particular context of the exercise of the powers conferred on them by the relevant internal market and environmental rules, to take appropriate measures to prevent specific potential risks to public health, safety and the environment, by giving precedence to the requirements related to the protection of those interests over economic interests.[14] It follows that 'where there is uncertainty as to the existence or extent of risks to human health, protective measures may be taken',[15] even if 'it proves impossible to carry out as full a risk assessment as possible in the particular circumstances of a given case because of the inadequate nature of the available scientific data'.[16]

Article 1(4) of the PPPR refers expressly to the primary law principle, which empowers the EU institutions 'to take appropriate measures to prevent specific potential risks to public health and safety'.[17] Furthermore, recital 8 of the preamble to the PPPR states that the PP should be applied and that the regulation aims to ensure that undertakings demonstrate that substances in products manufactured or placed on the market have no harmful effects on human or animal health and no unacceptable effects on the environment.

Since the PP is binding on the EU institutions and on the Member States when their measures fall within the scope of secondary law, the EU courts may be called on to review whether restrictive measures on hazardous substances or authorisations for the placing on the market of hazardous substances are compatible

10. The PPPR lays down the procedure for the renewal of the approval of active substances submitted under Article 14. The list of those substances is established in Commission Implementing Regulation (EU) No 686/2012 of 26 July 2012 allocating to Member States, for the purposes of the renewal procedure, the evaluation of the active substances whose approval expires by 31 December 2018 at the latest Text [2012] OJ L200/5.
11. EFSA gives independent scientific advice on regulatory issues, including approval of active substances to the European Commission and Member States based on risk assessments. See recitals 47 to 50 and art 22(2) of Regulation (EC) 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety [2002] OJ L31/1.
12. Commission Implementing Regulation (EU) 2021/2049 renewing the approval of the active substance cypermethrin as a candidate for substitution in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) 540/2011 [2021] OJ L420/6, at 6.
13. Consolidated versions of the Treaty on European Union and the Treaty on the Functioning of the European Union [2012] OJ C 326/01.
14. Case T 392/02 *Solvay Pharmaceuticals* v *Council* [2003] EU:T:2003:277, at [121].
15. See Case C-157/96 *National Farmers' Union and Others* [1998] ECR I-2211, at [63], and Case C-180/96 *UK* v *Commission* [1998] ECR I-2265, at [99].
16. Case C-236/01 *Monsanto Agricoltura Italia SpA and Others* v *Presidenza del Consiglio dei Ministri and Others* [1998] EU:C:2003:431, at [111] and [112].
17. Cases T-429/13 and T-451/13 *Bayer CropScience AG and Others* v *Commission* [2018] T:2018:624, at [109].

with the principle. Accordingly, claimants regularly assert in their actions for annulment that EU institutions have violated PP requirements.[18]

In its 2018 peer review of the pesticide risk assessment of the active substance cypermetrhin,[19] the EFSA underscored the missing information as being required by the regulatory framework and identified four critical areas of concern ('*domaines crtiques de préoccupation*'): high risk to aquatic organisms, bees and non-target arthropods, batches used in the (eco)toxicological studies could not be concluded as representative of the technical specification. In response to PAN Europe's request for an internal review, in February 2022 the Commission asked the EFSA to provide technical and scientific assistance concerning all of the relevant scientific issues raised in the request for internal review submitted by the NGO.

In March 2022, the EFSA published a technical report, which was limited to examining one single complaint put forward by the applicant NGO, concerning the failure to take account of certain studies within the independent literature when examining the endocrine disrupting properties of the active substance.

In July 2022, the Commission issued its decision, which contained an annex setting out the reasons for rejecting PAN's application for internal review.

Interaction between the precautionary principle and the obligation to ensure a high level of protection for human health and the environment

PAN submitted a single plea in law to the General Court alleging a breach of the PP and the Union's obligation to ensure a high level of protection for human health and the environment. This obligation to ensure a high level of protection is expressly set out in article 4 of the PPPR. This single plea in law was divided into two parts. The first part was directed against the preliminary remarks, while the second part was directed against the specific reasons put forward by the Commission in title II of the annex for rejecting the seven complaints raised by the applicant in its request for internal review.

The applicant took the view that if the risk had been established with sufficient certainty or if any uncertainties had not yet been resolved, the European Commission could not disregard the conclusions of the EFSA's RA by relying on its powers as risk manager.[20] It was, therefore, not possible for the Commission to renew the authorisation for the active substance. Admittedly, the renewal of approval for the substance cypermethrin would have been accompanied by European Commission 'risk mitigation measures'. However, the applicant considered that the Commission had discharged its responsibilities by deferring the determination of 'risk mitigation measures' to the Member States, within the context of the procedure for issuing authorisations for plant protection products.[21] In this way, the measures in question were no longer set *ex ante* but *ex post.*

Challenging the broad discretion granted to the European Commission in achieving the objectives set out in the pesticides legislation

The action was upheld as admissible. The General Court held, as a matter of principle, that wherever the EFSA had identified critical areas of concern, the Commission could not renew the approval of the active substance unless mitigation measures could (i) effectively and not theoretically and (ii) according

18. For an overview of this case law, see N. de Sadeleer, *Environmental Principles* (2nd ed. OUP, 2020) 192–221.
19. EFSA et al, 'Peer review of the pesticide risk assessment of the active substance cypermethrin' (2018) 16 EFSA Journal 8 5402.
20. PPPR, art 75.
21. Ibid. chapter III

to a sound scientific method reduce the risk to a level deemed to be 'acceptable'.[22] This interpretation is underscored by the PP.[23]

The General Court went on to point out that the broad discretion granted to the European Commission in achieving the objectives set out in the PPPR is not immune to judicial review. Specifically, the Court of Justice of the European Union (CJEU) verifies whether the relevant procedural rules have been complied with, whether the facts accepted by the Commission have been accurately stated and whether there has been a manifest error of appraisal or a misuse of powers.[24]

It was in the light of these clarifications concerning the scope of its judicial review that the General Court assessed the two parts of the applicant's single plea in law. As regards the first part, concerning the preliminary remarks contained in title I of the annex to the contested decision, the General Court dismissed the applicant's complaints concerning the Commission's role as a risk manager and the violation of requirements stemming from the PP.[25]

The General Court followed its previous case law on reviewing the European Commission's decision to use several phthalates: the PP, as laid down in Article 191(2) TFEU 'does no more than define the general environmental objectives of the European Union, … While it is true that that principle may warrant the adoption of a restrictive measure by an institution, it does not require it to do so'.[26] This reasoning stands in stark contrast to that followed by the CJEU in order to guarantee a high level of environmental health protection.

It is settled case law that the provisions of the PPPR are based on the PP. It follows that the Commission can invoke the PP where there is scientific uncertainty concerning risks posed by active substances.[27] Along the same lines, the Member States may apply that principle where there is scientific uncertainty as to the risks with regard to human or animal health or the environment posed by plant protection products to be authorised in their territory.[28] In this context, the PP justifies the adoption of restrictive measures. However, as will be explained below, the principle does not offer unfettered discretion to the EU institutions or to the Member States.

As regards the second part of the plea in law, the General Court dismissed the seven complaints put forward by the applicant in its application for internal review.

The first complaint concerned the failure to take account of the critical areas of concern voiced by the EFSA (representativeness of the batches of pesticides used, risks for aquatic organisms, non-target arthropods, and honey bees).[29] The Court dismissed the claimant's arguments that called into question the Commission's analysis of the representativeness of the batches of pesticides used and the consideration of the high risk to aquatic organisms, non-target arthropods and honeybees, issues of concern that were identified by the EFSA in 2018.[30]

The second complaint focused on the lack of knowledge of the scientific criteria for determining endocrine disrupting properties.[31] The applicant took the view that the Commission should have considered the

22. Ibid. art 104.
23. Ibid. art 91.
24. See Case 98/78 *Racke* v *Hauptzollamt Mainz* [1979] ECR 69, at [5], and Case C 16/90 *Detlef Nölle v Hauptzollamt Bremen-Freihafen* [1991] ECR I 5163, at [12]; Case 98/78 *Industrias Químicas del Vallés* v *Commission* [2018] EU:C:2007:443, at [76].
25. *PAN Europe* v *Commission*, above n. 8, at [57] to [118].
26. Case T 108/17 *ClientEarth* v *Commission* [2019] EU:T:2019:215, at [284].
27. Case C 499/18 *Bayer CropScience AG and Bayer AG* v *Commission* [2021] EU:C:2021:367, at [79].
28. *Blaise and Others*, above n. 7, at [44].
29. See *PAN Europe* v *Commission*, above n. 8, at [129] to [247].
30. Ibidem.
31. *PAN Europe* v *Commission*, above n. 8, at [248] to [249].

new criteria[32] under Regulation 2018/605, which sets out scientific criteria for determining endocrine disrupting properties.[33] The General Court dismissed this complaint.[34] According to the Court, EFSA, reckoning on the relevant scientific literature, had concluded that the potential for endocrine disruption could not be determined.[35] The Commission thus followed the EFSA's conclusions in considering that it was 'unlikely that cypermethrine is an endocrine disruptor'.[36] In addition, the Court took the view that requirement placed on the operator to provide confirmative data within ten years may trigger a reassessment of possible endocrine disrupting properties.[37] The applicant also highlighted in its second complaint the lack of data on endocrine disruption and the Commission's failure to take account of the Benaki scientific study,[38] which was carried out at its request as part of the process of drawing up criteria for endocrine disruptors. Stressing that the European Commission did not consider it useful to follow up this impact study during the cypermethrin active substance renewal process, the General Court dismissed this argument.[39] Finally, the applicant referred to the concerns expressed by several Member States as well as the significant doubts regarding endocrine disrupting properties of the substance at hand.[40] In this respect, France had pointed out that the EU studies concluding that the endocrine disturbance of cypermethrin was marginal were insufficient. However, the General Court considered that the applicant's arguments were contextual in nature.[41] Finally, the applicant's argument that the Commission had not taken independent scientific literature into account failed.[42]

The third complaint concerned a failure to take into account the lack of data identified by the EFSA. As a result, the scientific uncertainty about the substance's impact on bees and the endocrine system should have triggered application of the PP. Thus, according to the applicant, the Commission could not invoke its role as risk manager to dismiss such uncertainties without providing specific reasons.[43] The General Court dismissed this complaint as unfounded.

The fourth complaint objected that the European Commission could request the undertaking to present 'confirmatory information' in accordance with para 2.2. of Annex II to the PPPR where these data should have been included in the undertaking's renewal submission file. In accordance with para 2.2, requests for 'confirmatory information' may only be made in 'exceptional cases'. The applicant pointed out that the European Ombudsman had criticised the European Commission's overuse of such requests. The General Court pointed out that the Ombudsman's findings regarding the existence of an 'act of misadministration' did not have the effect of binding the court. Such findings could only constitute a hint of the Commission's breach of the principle of good administration.[44] The fourth complaint was also dismissed.[45]

The fifth complaint addressed the Commission's failure to take independent scientific data into account. The applicant invoked *Blaise* in this regard. In *Blaise*, the CJEU indicated that greater weight should not

32. Ibid. at [248].
33. Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties, OJ L 101, 2018, p. 33.
34. See *PAN Europe* v *Commission*, above n. 8, at [99] to [102].
35. Ibid. at [249].
36. Ibid. at [249].
37. Ibid.
38. Ibid. at [278].
39. Ibid. at [281].
40. Ibid. at [283].
41. Ibid. at [285].
42. Ibid. at [296] to [305].
43. Ibid. at [307].
44. Ibid. at [328].
45. Ibid. at [329] to [365].

systematically be given to regulatory studies and that the most recent studies should be taken into account.[46] The General Court dismissed it as partly unfounded and partly inadmissible.[47]

The sixth complaint alleged that an outdated approach had been applied to insect risk assessment, which failed to demonstrate any negative effects on non-target arthropods. The Court also rejected this complaint as partly unfounded and partly inadmissible.[48] Accordingly, the obsolete nature of the guidance document on ecotoxicology has not made it any less relevant.[49]

Lastly, the seventh complaint concerned the failure to examine the long-term toxicity of the representative formulation submitted by the claimant. The Court rejected all the arguments put forward by the applicant in support of its last complaint.[50]

Incidence of the determination of the level of protection in the pesticides legislation on the Commission's discretionary powers

The judgment at hand raises four fundamental issues. Firstly, the policy pursued by the European Commission appears to be somewhat inconsistent. Specifically, the Commission's decision to approve the substance cypermethrin stands in stark contrast to several of its previous decisions. For instance, the Commission decided to ban flupyrsulfuron-methyl, a substance used as a weedkiller in cereal crops, based on the EFSA's RA, which had highlighted problems of carcinogenicity and toxicity. In this case, the Commission, like the EFSA, relied on the PP to ban the molecule. With respect to the case at hand, it should be noted that EFSA had voiced a number of doubts concerning the problems encountered. As regards the presence of the molecules in groundwater, the EFSA had concluded that it was impossible to exclude the possibility that there could be unacceptable effects on water and harmful effects on human health.[51] Furthermore, in requiring the Member States to flesh out mitigation measures, the European Commission compounds centrifugal forces and undermines the effectiveness of the EU centripal regulatory process.

Secondly, from a constitutional point of view, under the terms of articles 114(3), 168(1), 169(3) and 191(2) of the TFEU as well as articles 35 and 37 of the Charter of Fundamental Rights, EU institutions and the Member States must ensure a high level of protection for human health, consumer protection and the environment. It is settled case law that 'the responsibility for determining the level of risk which is deemed unacceptable for society lies, …, with the institutions responsible for the political choice of determining an appropriate level of protection for society'.[52] Although this level does not technically need to be the highest that is technically possible, the EU institutions may be required to take preventive measures despite the existing scientific uncertainty.[53] Accordingly, risk management presupposes that the authorities determine from the outset 'the level of protection which they deem appropriate for society'.[54]

Consequently, recourse to the PP depends on the level of protection chosen by the competent authority when exercising its discretion, without however calling into question the pre-eminence of the protection of health and environmental interests.[55] Although the European Commission, as a risk manager, must 'take

46. *Blaise and Others*, above n. 7, at [94].
47. *PAN Europe* v *Commission*, above n. 8, at [367] to [382].
48. Ibid. at [398] to [408].
49. Ibid. at [385].
50. Ibid. at [409] to [435].
51. Case T-719/17 *FMC* v *Commission* [2021] EU:T:2021:143.
52. *Du Pont de Nemours*, n. 2 above, at [145].
53. Case C-284/95 *Safety Hi-Tech Srl* v *S. & T. Srl.* [1998] ECR I-4301, at [49].
54. Case T-13/99 *Pfizer Animal Health SA* v *Council* [2002], ECR II-1961 at [151].
55. *PAN Europe* v *Commission*, above n. 8, at [73]

into account' the conclusions of the RA,[56] it is not obliged to follow experts' conclusions. While we agree with this case law, the fact remains that the room for manoeuvre available to the Commission, as a risk manager, tends to be reduced as a result of the choices made by EU lawmakers. Given that in adopting the PPPR, EU lawmakers decided to pursue a particularly high level of protection buttressed by scientific principles underpinning the decision-making process, the bar has been set very high, with respect to both active substances as well as plant protection products.

In accordance with article 4(1) of the PPPR, an active substance can be approved where it complies with the criteria set out in Annex II. Under the terms of articles 4(3) and 29(1), a plant protection product shall only be authorised where it complies with a number of environment and health requirements.

Furthermore, the prioritisation by EU lawmakers within the PPPR of the protection of health or the environment over economic considerations enhances the role played by the PP. As a result, the weight to be given to scientific conclusions, to the EFSA experts' concerns and to any lingering uncertainty is much greater than in other EU regulatory acts. The fact that an array of 'Critical Areas of Concerns' has been identified by EFSA does not deprive the European Commission of its regulatory power to weigh up the various interests at stake, and the number and sheer importance of these issues significantly reduces its discretion. It follows that the PP is a criterion of legality that cannot be dismissed out of hand.

Thirdly, in spite of the areas of concern identified by the EFSA, the General Court took the view that the applicant was nevertheless obliged to present 'factual elements or the substantial legal arguments' capable of establishing 'plausible doubt' regarding the Commission's appraisal.[57] In so doing, the General Court rejected the view that the PP could shift the burden of proof, or at least attenuate the burden of proof. This reasoning seems to contradict the thesis defended by the General Court in paragraph 92 of its judgment according to which, when the RA identifies several areas of concern, the Commission should not depart from the scientific conclusions as to do so would entail a violation of the PP.

Fourthly, a formal interpretation of the PP only reveals the limits of the pesticides regulatory scheme. The fact that the Commission is counting on the Member States to adopt more specific mitigation measures in order to avert the risks does not mean that these measures will be adopted and properly or effectively implemented. Similarly, the fact that any decision will include guarantees as to its subsequent implementation by the Member State authorities does not mean that the PP will be properly complied with.

Declaration of conflicting interests

The author declared no potential conflicts of interest with respect to the research, authorship and/or publication of this article.

Funding

The author received no financial support for the research, authorship and/or publication of this article.

56. Article 14(1), 2nd indent of Implementing Regulation 844/2012.
57. PPPR, art 146.